

NEW DIRECTIONS IN PAIN RESEARCH: I

Release Date: September 4, 1998

PA NUMBER: PA-98-102

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National Institute of Neurological Disorders and Stroke

National Institute of Dental Research

National Cancer Institute

National Institute on Aging

National Institute of Allergy and Infectious Diseases

National Institute of Arthritis and Musculoskeletal and Skin Diseases

National Institute on Deafness and Other Communication Disorders

National Institute on Drug Abuse

National Institute of General Medical Sciences

National Institute of Nursing Research

Office of Research on Women's Health

PURPOSE

The National Institute of Neurological Disorders and Stroke (NINDS) and the National Institute of Dental Research (NIDR), serving as the lead Institutes for the National Institutes of Health (NIH) Pain Research Consortium, together with the National Cancer Institute (NCI), National Institute on Aging (NIA), National Institute of Allergy and Infectious Diseases (NIAID), National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), National Institute on Deafness and Other Communication Disorders (NIDCD), National Institute on Drug Abuse (NIDA), National Institute of General Medical Sciences (NIGMS), National Institute of Nursing Research (NINR), and the Office of Research on Women's Health (ORWH), encourage investigator-initiated research project grant applications to study mechanisms underlying analgesic response and pain to advance the development of novel pain interventions, treatments and management strategies. The purpose of this New Directions in Pain Research: I program announcement (PA) is to inform the scientific community of broad, shared interests in pain research encompassing the various components of the NIH, and to stimulate and foster a wide range of basic, translational and patient-oriented clinical studies on pain. Applications are particularly encouraged to study pain throughout the lifespan from the perspectives of molecular genetics, transcriptional controls,

signal transduction, including cellular/molecular mechanisms, innovative imaging technologies, plasticity and from hormonal or gender influences. The pain experience needs to be examined at all levels of analysis from the gene, molecule, cell, tissue, and organ, to the individual, family and community, with the ultimate goal of developing new insights into pain intervention, treatment and management.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This PA, New Directions in Pain Research: I, is related to the priority areas of chronic disabling conditions, cancer, and clinical prevention services. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0 or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-512-1800).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by foreign and domestic, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Racial/ethnic minority individuals, women, and persons with disabilities are encouraged to apply as principal investigators.

MECHANISM OF SUPPORT

The mechanism of support will be the research project grant (R01). Applicants are strongly encouraged to contact the program official listed under INQUIRIES for information. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. Awards will be administered under PHS grants policy as stated in the Public Health Service Grants Policy Statement (April 1, 1994).

RESEARCH OBJECTIVES

Background

Pain is a significant national health problem. It is the most common reason individuals seek medical care, with millions of medical visits annually; costing the American public more than \$100 billion each year in health care, compensation and litigation. Some studies suggest that more than a third of the American population suffers from a chronic pain condition at some point in their life. Pain-related disability presents a significant and costly liability to workers, employers and society. In the workplace, a significant proportion of employees, about 14%, take time off from their jobs due to pain conditions. In hospitalized patients, pain has been associated with increased length of stay, longer recovery time, and poorer patient outcomes, all of which have health care quality and cost implications. Pain, therefore, has a profound impact on the quality of life and health-associated costs for all Americans.

Significant progress is being made in understanding the neurobiology of pain. New approaches to more effective diagnostic tools as well as treatment and management strategies, offer unique scientific challenges. Individuals during development and aging, may react in very different ways to pain, perhaps due to the influence of genetic differences, gender, hormones, and/or past experiences. Thus, pain needs to be studied at all levels of basic and clinical research, including the gene, molecule, cell, tissue, and organ, and individual, with the ultimate goal of developing innovative approaches to intervention and management of pain.

In order to develop a Trans-NIH research agenda, NIH sponsored a major Symposium: "New Directions in Pain Research," in November 1997. This meeting, under the aegis of the NIH Pain Research Consortium, resulted in the identification of research needs reflecting recommendations from a broad spectrum of the scientific community expert in pain and non-pain research.

Scope of Research Sought

Basic, translational, and patient-oriented clinical research on pain is solicited through this program announcement. The areas in which pain research is encouraged cuts across the interests and missions of many NIH Institutes, Offices, Centers and programs. Applications should not be limited to these topics or viewed as restricted to only one specific Institute, Office or Center. Current NIH referral guidelines will be used to assign grant applications to the most appropriate NIH Institute based on the scientific focus of the application.

The following examples are provided as topics falling within the scope of this program announcement. These examples are presented illustratively, are not exclusive, and are not presented in any particular priority order.

- o Investigation of the genetic contribution of differences in pain response, perception and modulation, using tools such as quantitative trait locus analysis for identifying genes that contribute to complex traits and diseases, such as pain.
- o Development of new model systems of the molecular genetics of pain transmission, modulation and perception, that would include individual and multiple gene mapping, transgenic animal models, and studies of individual and multiple gene expression.
- o Exploration of the neuromolecular basis of pain, by investigating targets in signal transduction pathways, e.g., calcium, potassium or sodium ion channels, that may be the most effective points for drug development and intervention.
- o Exploration of the role of second messenger systems, including G protein-coupled receptors and protein kinases, in pain transmission and modulation.
- o Expansion of research on neuroimaging of pain, including analytical techniques for the study of structural and functional correlates of pain perception, particularly for diagnostic purposes.
- o Research on neuroplastic processes as these relate to the development and persistence of chronic pain conditions.
- o Mechanisms underlying differences in pain and analgesic response due to hormonal or gender-related factors.

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing research involving human subjects should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research", which have been published in the Federal Register of March 28, 1994 (FR 59 14508-14513), and in the NIH GUIDE FOR GRANTS AND CONTRACTS of March 18, 1994, Volume 23, Number 11.

Investigators may obtain copies from these sources or from the program staff or contact person listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

NIH POLICY AND GUIDELINES ON THE INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are specific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" that was published in the NIH Guide for Grants and Contracts, March 6, 1998, and is available at the following URL address: <http://www.nih.gov/grants/guide/notice-files/not98-024.html>

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev.5/95) and will be accepted at the standard application deadlines as indicated in the application kit. Application kits are available at most institutional offices of sponsored research and may be obtained from the Division of Extramural Outreach and Information Resources, National Institutes of Health, telephone (301) 435-0714; Email: asknih@od.nih.gov. The title and number of the PA must be typed in Section 2 on the face page of the application.

The completed original application and five legible copies must be sent or delivered to:

CENTER FOR SCIENTIFIC REVIEW
NATIONAL INSTITUTES OF HEALTH
6701 ROCKLEDGE DRIVE, ROOM 1040 - MSC 7710
BETHESDA, MD 20892-7710
BETHESDA, MD 20817 (for express/courier service)

REVIEW CONSIDERATIONS

Applications will be assigned on the basis of established PHS referral guidelines. Applications that are complete will be evaluated for scientific and technical merit by an appropriate peer review group convened in accordance with the standard NIH peer review procedures. As part of the initial merit review, all applications will receive a written critique and undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed, assigned a priority score, and receive a second level review by the appropriate national advisory council or board.

Review Criteria

The goals of NIH-supported research are to advance our understanding of biological systems, improve the control of disease, and enhance health. In the written review, comments on the following aspects of the application will be made in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. Each of these criteria will be addressed and considered in the assignment of the overall score.

(1) Significance. Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

(2) Approach. Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

(3) Innovation. Does the project employ novel concepts, approaches or method? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

(4) Investigator. Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?

(5) Environment. Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

The initial review group will also examine the provisions for the protection of human and animal subjects and the safety of the research environment.

AWARD CRITERIA

Applications will compete for available funds with all other approved applications assigned to that institute/center (IC). The following will be considered in making funding decisions: quality of the proposed project as determined by peer review, availability of funds, and program priority.

INQUIRIES

Inquiries concerning this program announcement are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

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AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance Nos. 93.131, 93.279, 93.846, 93.853, and 93.854. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The PHS strongly encourages all grant and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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